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In the
Supreme Court of the United States

OCTOBER TERM, 1995

HUGH EDWARD ENGLISH, III and
LORRAINE ENGLISH,
Petitioners

v.

MENTOR CORPORATION,
Respondent

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED FOR REVIEW

Do the Medical Device Amendments of 1976 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §360c *et.seq.*, preempt all state law claims stemming from the sale of Class III medical devices which have never been granted official approval by the Food and Drug Administration for safety and effectiveness?

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REFERENCE TO OPINIONS OF LOWER COURTS

The Opinion of the Third Circuit Court of Appeals is reported at 67 F.3d 477 (1995). The decision of the United States District Court for the Eastern District of Pennsylvania was rendered by way of Memorandum and Order filed June 13, 1993 and is not reported.

STATEMENT OF JURISDICTION

The judgment of the United States Court of Appeals for the Third Circuit was entered on September 29, 1995. The statutory provisions which confers jurisdiction upon this Honorable Court to review the issues presented herein by Writ of Certiorari is 28 U.S.C. §1254(1).

STATEMENT OF STATUTES AND REGULATIONS INVOLVED IN THE CASE

The verbatim text of the following statute and regulations are provided in the Appendix attached hereto: 21 U.S.C. §360k; 21 C.F.R. §§807.97, 807.100(b), 808.1(d).

STATEMENT OF THE CASE AND BASIS OF FEDERAL JURISDICTION

The product which is the subject of this litigation is a medical device known as a GFS Inflatable Penile Prosthesis ("GFS IPP") which was manufactured and marketed by

Mentor. The GFS IPP is subject to Food and Drug Administration ("FDA") scrutiny pursuant to the Food, Drug and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. §301, *et.seq.* and the 1976 Medical Device Amendments ("MDA"), 21 U.S.C. §360c, *et.seq.* The MDA provides for preemption of state law regulatory action which is "different from" or "in addition to" certain federal requirements created under the MDA. 21 U.S.C. §360k(a). There was no preemption under the original Act. On February 11, 1988, Mr. English was implanted with a GFS Inflatable Penile Prosthesis to correct the impotency he suffered as a result of diabetes. The implant functioned satisfactorily until it failed in the summer of 1991. Suit was originally brought in Pennsylvania state court on April 22, 1993 alleging negligent design, negligent manufacture, failure to warn, breach of warranty, and product liability claims based on state common law. Mentor removed to the United States District Court for the Eastern District of Pennsylvania pursuant to 28 U.S.C. §§1332 and 1441, diversity of citizenship with an amount in controversy in excess of $50,000. The district court granted Mentor's subsequent Motion for Summary Judgment, finding that each of English's claims were wholly preempted by §360k of the MDA even though the devices had entered the market pursuant to the pre-amendment 1938 FDCA through a unique "grandfathering" system created by the FDA.

English filed a timely Notice of Appeal to the Third Circuit which had jurisdiction under 28 U.S.C. §1291. The Third Circuit affirmed the preemption of all state law tort claims except breach of express warranty and in so doing departed from the holdings in two other circuits which have decided in whole or in part against preemption of state law claims involving similar medical devices.

Under the MDA, medical devices are classified by the FDA into one of three different categories: Class I devices which pose little or no threat to health, Class II devices which pose a greater risk to health and Class III devices which present potentially unreasonable risk of illness or injury. Class III devices are ordinarily required to undergo a thorough premarket approval ("PMA") process to assure safety and effectiveness by the FDA before the products are marketed. 21 U.S.C. §360c(a)(1)(C) and 360e. However, the FDA has adopted what is known as the "§510(k) notification procedure" to allow the marketing of products which are shown to be the "substantial equivalent" of products being sold before the enactment of the MDA when no PMA was required (but where consumers had judicial recourse when injuries occurred from defective products). 21 C.F.R. §§807.81-807.100. The GFS IPP is a Class III device. 48 Fed. Reg. 53012, 53024 (November 23, 1983). Although the FDA

has proposed a rule requiring PMA for penile implants, it has never been adopted [58 Fed. Reg. 25902 (April 28, 1993)] and the FDA has never granted PMA for Mentor's GFS Inflatable Penile Prosthesis. Rather, Mentor's GFS IPP which is the subject of this action was given substantial equivalence status by the FDA on August 26, 1987.

The abbreviated §510(k) procedure bypasses many of the premarket approval procedures mandated by Congress (as set out at 21 U.S.C. §360e; 21 C.F.R. §814.45(c)) and does not assure reasonable safety and effectiveness of products submitted to the FDA under the modified notification procedure set forth in 21 C.F.R. §807.81-807.100 and 21 U.C.S. 360c(f) and (i). In its own regulations, the FDA has explicitly stated that any product granted substantial equivalency status does not have official approval by the FDA. 21 C.F.R. §807.97.

The FDA has never adopted requirements concerning the safety and effectiveness of IPPs, still does not require PMA of IPPs and yet the decision of the Third Circuit, in direct conflict with two other circuits, leaves consumers without any protection and without any recourse for defective devices.

ARGUMENT

The question concerning the extent of preemption under §360k of the MDA has come under consideration by trial and appellate courts virtually across the country. The decisions vary from jurisdiction to jurisdiction. More and more consumers are being harmed as more and more medical devices fail and an injured party in one jurisdiction may have judicial recourse while another in an adjoining jurisdiction is without remedy. This lack of uniformity is in need of clarification from the United States Supreme Court in order that justice be distributed with an even hand throughout the land.

The inconsistent decisions have developed as lower courts have attempted to interpret the preemptive meaning of §360k of the MDA. The focal question becomes to what extent, if any, does the MDA create requirements which are considered to be "different from" or "in addition to" the state law claims being asserted in the courts by injured plaintiffs against product manufacturers. The inconsistent opinions rendered by the various circuit courts have depended upon two variables: 1) the classification of the concerned device and the method by which it reached the market and 2) the differing analyses employed by the various courts to determine when preemption is triggered under §360k. The

first variable is easy to categorize: 1) class II devices (where no PMA is required under the MDA), 2) class III PMA products, and 3) class III §510(k) products. It is the second variable in the context of cases involving the last category of devices - the class III §510(k) devices which have been granted substantial equivalence status and put on the market without official FDA approval - which has caused the greatest divergence among the courts and which is presented herein.

A. THE EXISTENCE OF FEDERAL REGULATIONS IS A PREREQUISITE TO PREEMPTION OF STATE LAW CLAIMS.

The preliminary question asked by courts has been what is meant by "state requirement" in the context of §360k. It is generally agreed that the state common law claims asserted in personal injury law suits are included in the first use of the word "requirement" in §360k. *See Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), cert. denied, ___ U.S. ___, 113 S.Ct. 327 (1992); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1342 (11th Cir. 1995). Even on this issue, however, there is conflict among the circuits as in *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1457 (9th Cir. 1995), where the court concluded that state common law of general applicability including claims for damages is not necessarily included in the definition of the first use of the word

"requirement" in §360k. This is an issue which requires clarification from this Honorable Court. The second prerequisite to triggering preemption set forth in §360k is the existence of a requirement created under the MDA applicable to the device at issue. It is this question of whether the MDA establishes requirements sufficient to trigger preemption which has created the most conflict among the numerous courts which have faced the issue.

The two seminal cases coming out of the First Circuit and the Fifth Circuit which imposed total preemption pursuant to the MDA involved Class III devices which had undergone the complete premarketing approval process. *See King v. Collagen*, 983 F.2d 1130 (1st Cir. 1992) and *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993). Their holdings are predicated on the notion that the PMA procedures mandated by the MDA "subject [the product] to the most extensive premarketing approval ***requirements*** imposed by the MDA...designed to provide a 'reasonable assurance of...safety and effectiveness' for medical devices... [emphasis added]" and therefore any state law liability claim is preempted. *King*, 983 F.2d at 1131.

The *Stamps* court took steps to explicitly distinguish a device which has undergone premarket approval from a "substantially equivalent" device. *Stamps*,

984 F.2d at 1422 and 1423. In *Stamps*, the court cited *Larsen v. Pacesetters Systems*, 837 P.2d 1273 (Haw. 1992), which held that there was no preemption for "a device that passed through a less stringent Class III review process by virtue of its being 'substantially equivalent' to devices already allowed to be marketed." *Stamps*, 984 F.2d at 1423, fn. 6. *Stamps* and *King*, which came later than *Larsen*, dealt with devices which had undergone the vigors of premarket approval and are therefore distinguishable but, importantly, do not reject *Larsen*. If anything, *Stamps* adopts *Larsen* and uses it to limit its holding to only those instances where the device has been subject to the requirements imposed by the PMA process.

The 11th Circuit in *Lohr v. Medtronics, Inc.*, 56 F.3d 1335 (11th Cir. 1995), adopted a two step test which is in concert with the *Stamps/King* analysis to determine if the preemptive language found in §360k applies to a particular device. First, the court looks at what constitutes a requirement under the MDA. Second, the court compares the state requirements under which the action was brought to the MDA requirements, if any, to determine if the state law claims are "different from" or "in addition to" and relate to any matter included in a specific MDA requirement. 56 F.3d at 1347.

Relying upon this Honorable Court's rulings in *Nations Bank of N.C., N.A. v. Variable Annuity Life Ins. Co.*, ___ U.S. ___, 115 S.Ct. 810, 813 (1995) and *Chevron, U.S.A., Inc. v. Natural Resources Defense Counsel, Inc.*, 467 U.S. 837, 841-43 (1984), the *Lohr* court reached the conclusion that "the scope of the word 'requirement' is ambiguous and consideration of the FDA's interpretation is appropriate." 56 F.3d 1344. The *Lohr* court's reliance of FDA interpretation of §360k is consistent with *Stamps, supra; Slater, supra; Larsen, supra; Moore v. Kimberly-Clark Corporation*, 867 F.2d. 243 (5th Cir. 1989); *Mulligan v. Pfizer*, 850 F.Supp. 633 (S.D. Ohio 1993); *Lamontagne v. E.I. DuPont DeNemours & Company*, 834 F.Supp. 576 (D. Conn. 1993) and *Elbert v. Howmedica*, 841 F.Supp. 327 (D. Haw. 1993).

The Supreme Court has afforded considerable attention to the interpretation of preemption provisions by the federal agency assigned to enforcement of the preempting statute. *See Chevron United States, Inc. v. Natural Resources Defense Counsel, Inc.*, 467 U.S. 837 (1984); *Bowels v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945). In *Fidelity Federal Savings and Loan Association v. DeLaCusta*, 458 U.S. 141 (1982), the U.S. Supreme Court counselled lower courts to defer to regulatory agency interpretation which carries great weight in deciding the preemptive effect of federal

statutes. In *Chevron, supra*, this Honorable Court also ruled that agency interpretation is controlling provided it is reasonable. 467 U.S. 837, 843 (1984).

FDA's interpretation of the preemptive language of §360k is as follows: "state or local requirements are preempted **only** when the Food and Drug administration has established **specific** counterpart regulations or there are other **specific** requirements applicable to a **particular** device under the act...[emphasis added]." 21 C.F.R. §808.1(d).

In determining what constitutes a specific requirement under the MDA, the *Lohr* court limited its scope of review to "a Class III device which entered the market via the 510k process as the substantial equivalent of a grandfathered device [device already on the market at the time the MDA was enacted]." 56 F.3d at 1335. At odds with the Third Circuit's subsequent decision in this case, the Eleventh Circuit held that "nothing in the MDA's §510(k) approval procedures, grandfathering provision, oversight and enforcement powers or classification requirements constitutes a 'specific requirement' justifying preemption under the Act" of state law defective design claims. 56 F.3d at 1350. The *Lohr* court did conclude that plaintiffs' negligent manufacturing and failure to warn claims were preempted by virtue of the existence of

specific requirements pertaining to both good manufacturing practices and labeling found in the MDA and FDA regulations respectively at 21 U.S.C. §360j(f), 21 C.F.R. §§820.1-820.198, 21 C.F.R. §§801.109(b), (c), 807.87(e). 56 F.3d at 1331 and 1350.

The case of *Feldt v. Mentor Corporation*, 61 F.3d 431 (5th Cir. 1995), involved the GFS IPP which is herein concerned and presents the identical legal issues. The Fifth Circuit, in conformity with the analyses used in *Stamps* and its progeny (but at odds with the decision in *Kennedy, supra*) concluded that the state common law theories being asserted by plaintiff are requirements relating to safety and effectiveness, thus meeting the first prerequisite to preemption under §360k. 61 F.3d at 434. However, as similarly concluded in *Lohr, supra*, the *Feldt* Court held that the §510(k) process does not impose any requirement with regard to product design. *Id.* at 437.

Where the FDA has imposed warning and labeling requirements as with Class II devices, the courts have stricken state law claims founded on inadequate warning and labeling. But, in the absence of FDA requirements or approval going to design, composition and construction, as with Class II devices, the courts have held that preemption does not apply with respect to

state law claims going to these areas of liability. *See Moore v. Kimberly-Clark Corporation*, 867 F.2d 243 (5th Cir. 1989). *Moore* and its progeny uses an analysis which is consistent with *Stamps*, *King*, *Lohr* and *Feldt*, *supra*.

B. IN DIRECT CONFLICT WITH THIS COURT'S MANDATES ESTABLISHING A STRONG PRESUMPTION AGAINST PREEMPTION AND IN CONFLICT WITH NUMEROUS OTHER CIRCUIT DECISIONS, THE THIRD CIRCUIT HAS PREEMPTED STATE LAW CLAIMS.

Only where there is "an unambiguous congressional mandate to that effect" should courts preempt state law. *Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 144 (1963). In *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), this Honorable Court cautioned that any consideration of federal preemption "start[s] with the assumption that the historic police powers of the states are not to be superseded by a...federal act unless that [is] the clear and manifest purpose of Congress."

Any preemption discussion is premised with the "presumption that state or local regulations of matters related to health and safety is not invalidated under the supremacy clause." *Hillsborough County v. Automated Medical Lab*, 471 U.S. 707, 715 (1985); accord, e.g., *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). The

Supreme Court has been reticent in finding complete preemption of all state law claims. *See Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). The party arguing in support of preemption "bears a heavy burden." *Pennsylvania Medical Society v. Marconis*, 942 F.2d 842, 846 (3d Cir. 1991). *See also Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). The burden is especially heavy when the state's interest in health and safety is concerned as in this case. *Hillsborough County v. Automated Medical Labs, Inc.*, 471 U.S. 707, 715 (1985). The presumption against preemption becomes stronger where dismissing traditional state law damages remedies would leave injured persons without any recourse. The Supreme Court stated in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 241 (1981) that "it is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." In *United Construction Workers v. Laburnum Construction Corp.*, 347 U.S. 656 (1954), the Supreme Court found no preemption where injured parties would be left without recourse.

Despite the presumption against preemption mandated by this Honorable Court, the Third Circuit held that (with the exception of breach of warranty claims) there is total preemption of state law claims because, apparently, the §510(k) process amounts to an MDA-created

requirement which is "different from" or "in addition to" the state law claims asserted by English. The Third Circuit in *English* explicitly relied on its rationale set down in its earlier decision of *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3rd Cir. 1995). That case, however, involved a product which had undergone the comprehensive PMA process. The *English* decision devotes a total of one paragraph in a seven page opinion in reaching its conclusion that §360k also preempts state common law actions for cases involving §510(k) devices. 67 F.3d at 480. In so doing, the Third Circuit has chosen not to adopt the first prong of the two part analysis employed by the Eleventh and Fifth Circuits in *Lohr* and *Feldt, supra*. That is, in contradiction to *Chevron, supra*, the *English* court rejects FDA interpretation of §360k found at 808.1(d) and the Third Circuit does not engage in a consideration of what specific requirements have been established with the adoption of the MDA with respect to devices which have entered the market via §510(k) notification only.

In expanding the preemptive effect of §360k to include §510(k) devices, the *English* court has ignored the important distinction between PMA and §510(k) notification. Premarket approval is granted upon a finding by the FDA that there is "reasonable assurance" that the device is safe and effective. 21 U.S.C. §360e(d)(2); 21 C.F.R. §814.20. The standards to

determine substantial equivalence was not codified until 1990 in 21 U.S.C. §360c(i). Currently, §510(k) substantial equivalence status is granted upon a finding that the proposed new product either has the same technological characteristics as a device marketed under the 1938 FDCA **or**, if different, has been demonstrated to be *at least as safe as* the predicate product. 21 C.F.R. 807.100(b)(2)(B). However, there is no way to determine which of these two alternative standards found in §360c(i) was used by the FDA to substantiate §510(k) status of Mentor's GFS IPP. Even if it was the latter standard - a showing of *at least as safe as* the predicate device - pre-amendment devices were not regulated with respect to safety and effectiveness since there was no FDA regulation. It is of great significance that before the MDA was enacted, there were no requirements under the 1938 FDCA with regard to FDA approval or regulation concerning product safety and efficiency which is now intended through the PMA process. In other words, a product entered the market absent any intervention from the FDA, but consumers had free access to the courts when harm was caused by a defective product. Therefore, any argument that the §510(k) process imposes MDA-created requirements of safety and effectiveness which would be duplicated if state law claims were not preempted fails to fully comprehend the significant differences between PMA and §510(k). In its own

regulations, the FDA has explicitly stated that any product granted substantial equivalency status does not have official approval of the FDA. 21 C.F.R. §807.97.

In the pre-amendment scheme found in the FDCA of 1938, Act of June 25, 1938, Ch. 675, 52 Stat. 1040, there was no premarket review process. In actuality, the current §510(k) notification system grandfathers Class III devices and in fact introduces them into the public domain under the pre-MDA 1938 standards where there is no preemption of state law claims for injuries caused by defective products. When a product reaches the market via §510(k), the public is deprived of any assurances of safety and effectiveness otherwise intended by the PMA process. To allow the Third Circuit's holding that consumers' judicial remedies are preempted by reason of the §510(k) approval process to stand would be blatantly unfair and have significant social consequences. In effect, the public subject to Third Circuit jurisdiction would continue to be deprived of any means of safety assurance and preemption would leave consumers without any remedy. Such a ruling would ignore the judicial precedent of this Honorable Court which establishes a strong presumption against preemption especially in those instances where the public is without remedy (*see Silkwood, supra.*) and would be in direct conflict with the other circuit

court decisions reached in *Lohr* and *Feldt*, *supra*.

CONCLUSION

For the foregoing reasons, this petition for certiorari should be granted to clarify the growing conflict among the numerous lower courts being faced with the issue herein presented.

Respectfully submitted,

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Filed September 29, 1995
UNITED STATES COURT OF APPEALS
FOR THE CIRCUIT

No. 94-1714

HUGH EDWARD ENGLISH, III; LORRAINE ENGLISH,
v.
MENTOR CORPORATION

ON APPEAL FROM THE
UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA
(D.C. Civil Action No. 93-02725)
Argued January 12, 1995
Before: COWEN, NYGAARD and ALITO,
Circuit Judges
(Opinion Filed: September 29, 1995)

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OPINION OF THE COURT

PER CURIAM.

Hugh and Lorraine English sued Mentor Corporation, alleging claims based upon strict product liability, negligence, breach of express and implied warranty, loss of consortium by Mrs. English, and punitive damages, Mr. English had a Mentor inflatable penile prosthesis implanted. The device malfunctioned and appellants sued Mentor in the Pennsylvania Court of Common Pleas. Mentor removed the case to the federal

district court, which granted summary judgment in its favor, holding that appellants claims were preempted by the Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§360c-360rr.

Appellants raise two issues on appeal: (1) whether the Medical Device Amendments of 1976 preempt their state law tort and contract claims against the manufacturer of a Class III medical device; and (2) whether the Amendments also preempt these claims for a medical device cleared for marketing under the "substantial equivalence" exception to the general rule requiring a full Premarket Approval process. We will affirm in part, reverse in part, and remand the cause.

I.

The Medical Device Amendments classify medical devices as Class I, II, or III devices, depending upon their potential danger to the public. Class III devices are the most dangerous, the most heavily regulated and include the prothesis implanted in Mr. English. Generally with Class III devices, the manufacturer must submit a detailed "Premarket Approval" application to the FDA, 21 U.S.C. §360e(c)(1), and obtain Premarket Approval before they can be marketed to the public. *Id.* §360c(a)(1)(C).

There are two exceptions to this requirement. First, Class III devices may receive an "Investigational Device Exemption" (or "IDE") from the FDA, *id.* §360j(g), which permits the device to be tested on human subjects without obtaining Premarket Approval. *Id.* § 360e(a). Second, absent formal premarket approval, the FDA

has permitted manufacturers to market *new* inflatable penile implants by completing the "510(k)" procedure, "which requires a demonstration that the new device is "substantially equivalent" to other penile implants already on the market before the passage of the MDA.[1] 21 U.S.C. §360c(f)(3);

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[1]In adopting the MDA, Congress drew a distinction between devices that were on the market before its passage (and devices "substantially equivalent" to these devices) and devices marketed after its passage in 1976. Congress realized that it was impracticable to require that devices that were already on the market be withdrawn until they obtained premarket approval from the FDA. *See* 21 U.S.C. §360e. Instead, Congress directed the FDA to promulgate regulations to allow manufacturers of these devices to move gradually into compliance with the MDA. *Id.* This authority also extendecd to new devices "substantially equivalent" to divices on the market as of 1976. *Id.*

The FDA relied on this distinction as authorization for its 510(k) process. Thus, the FDA has issued regulation, such as 21 C.F.R. §876, classifying certain preexisting devices (including inflatable penile implants) as Class III devices, but exempting them from immediate premarket approval (by postpoining the date the regulations become effective). The FDA also allows substantial equivalents of these devices to be marketed before obtaining final premarket approval--by completing the 510(k) process. *Id.* at §§807.81-807.100.

(continued...)

21 C.F.R. §§ 807.81-807.100. Absent such a demonstration, a device may not be marketed until obtaining the full premarket approval described above.

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[1](...continued)
These devices, however, are required to obtain premarket approval in the future. *See* 21 C.F.R. §870.1-870.3. New devices (i.e. devices not in existence before 1976 or substantially equivalent to such a device) must receive premarket approval before they may be marketed. 21 U.S.C. §360e(a); 21 C.F.R. §870.3.

With the passage of the Safe Medcial Devices Act ("SMDA") in 1990, Pub. L. No. 101-629, Congress explicitly codified these 510(k) procedures. *See* H.Rep. No. 101-808, 101st Cong., 2d Sess., 1990 U.S.C.C.A.N. 6305, 6319 ("Section 4(b) [of the SMDA] codifies the FDA's current practice regarding the use of the 510(k) procedure for entering the market."). The current approach is found at 26 U.S.C. §360c(f)(3), which explicitly allows a manufacturer of a Class III device, for which no final regulation requiring premarket approval has been promulgated, to market the device by complying with the FDA's 510(k) notification process. Similarly, the SMDA codified the FDA's definition of substantial equivalence. *See* 21 U.S.C. §360c(i)(1)(A). Because Congress in the SMDA codified FDA procedures in place at the time the device implainted into English as approved by the FDA pursuant to the 510(k) process, we make refernc to its provisions in determining the extent to which the FDA has regulated the device.

Under this 510(k) procedure, the FDA must decide whether a new device is in fact substantially equivalent to a device already on the market prior to 1976. *See* 21 U.S.C. § 360c(f)(3). Pursuant to 21 U.S.C. §360c(i)(1)(A), a device is considered "substantially equivalent" if the device:

> (i) has the same technological characteristics as the predicate device, or
>
> (ii)(I) has different technological characteristics and information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe as and effective as a legally marketed device, and (II) does not raise different questions of safety and efficacy than the predicate device.

This substantial equivalence determination therefore the manufacturer to provide information to the FDA in order to ensure that "the device is safe, effective and performs as well as or better than the [predicate] device...." 21 C.F.R. §807.95; *see* 21 U.S.C. §360c(i)(3)(A); 21 C.F.R. §807-92.

The FDA, however, views the 510(k) exception as an intermediate step to obtaining full premarket approval. The FDA

will eventually require all Class III devices to obtain full premarket approval.[2]

Before Mr. English's prosthesis was inserted, the FDA determined that Mentor's prosthesis was substantially equivalent to other Class III devices marketed before the Amendments, and allowed Mentor to market its prosthesis to the public without Premarket Approval. The FDA had initially granted an Investigational Device Exemption to Mentor, permitting it to test its prosthesis on human subjects; English, however, did not receive a device as part of an IDE test study and thus Mentor cannot rely on IDE regulations in support of its argument that English's state tort claims are preempted.

II.

Appellants argue first that Congress never intended the Amendments to preempt

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[2]Congress has directed the FDA to clear up the backlog of devices that are classified as Class III, but for which the FDA has not issued a final regulation requiring premarket approval. 21 U.S.C. §360e(i). Congress was concerned that the FDA was using the 510(k) process as a means to avoid having to issue premarket approval on a wide array of devices. *See* H.Rep. No. 101-808, 101st Cong., 2d Sess., *reprinted in* 1990 U.S.C.C.A.N. 6305, 6317-20. Under §360e(i), manufacturers of these Class III devices will have to submit information pertaining to their performance, including safety and effectiveness data. The FDA will then be required promptly to re-categorize these devices as Class II devices or finally issue regulations requiring that they obtain premarket approval. *Id.*

state law claims. We rejected that argument in *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S.Ct. 429 (1994); *see also Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir. 1995). The preemption provision provides:

> (a) Except as provided in subsection (b)[3] of this section, no State or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. §360k(a).

We opined in *Gile* that Congress' use of the word "requirement" in §360k(a) adequately expresses its intent to preempt state law claims that would impose different or additional requirements from those under federal law. 22 F.2d at 542-43. We held that §360k(a) preempted state law strict liability and negligence claims as impermissible attempts to impose additional

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[3]Subsection (b) permits a state to apply for an exemption form the preemption of subsection (a) for certain state laws. No such application was made in this case, thus subsection (b) is not at issue.

safety or effectiveness requirements on medical device manufacturers. *Id.* at 545. In *Michael*, we held that §360k(a) also preempts breach of implied warrant claims because they too arise under state law. 46 F.3d at 1324-25.

Applying *Gile* and *Michael*, we hold that the district court correctly adjudged appellants' strict liability, negligence, and breach of implied warranty claims preempted by §360k(a) of the Medical Device Amendments. Because *Gile* and *Michael* explain our rationale with respect to these claims, we need not.

In *Michael*, we held that breach of express warranty claims are not preempted by §360k(a) because they are created by the parties and not by state law. 46 F.3d at 1325-26; *see also Cipollone v. Liggett Group, Inc.*,___ U.S. ___, 112 S.Ct. 2608, 2622 (1992) ("[R]equirements imposed by an express warranty are not 'under state law,' but rather *imposed by the warrantor*."). Again. we are satisfied that our opinion in *Michael* fully sets forth our analysis. We will reverse the district court's summary judgment on this claim.

The remaining claims are for loss of consortium by Mrs. English and punitive damages. We will uphold summary judgment with to the latter, inasmuch as the Pennsylvania courts have held that, absent fraud, punitive damages cannot be awarded for a breach of warranty. *See e.g., AM/PM Franchise Ass'n v. Atlantic Richfield*, 526 Pa. 110, 584 A.2d 915, 927 (1992).

We have found no Pennsylvania case, however, deciding whether a loss of consortium award can be premised upon a breach of warranty. Pennsylvania has made

clear that loss of consortium cannot be based on pure breach of contract. *E.g., Thorsen v. Iron and Glass Bank*, 328 Pa.Super. 135, 476 A.2d 928, 932 (1984). Other courts, however, have looked to the substance of the breach of warranty claim in deciding whether it will support a loss of consortium award. *See, e.g., Scarzella v. Saxon*, 436 A.2d 358, 363 (D.C. App. 1981) (allowing loss of consortium premised upon breach of warranty and citing W. Prosser Law of Torts § 95, at 635 (4th ed. 1971) for the proposition that warranty actions have historically sounded in tort as well as contract); *Fernandez v. Union Bookbinding Co., Inc.*, 400 Mass. 27, 507 N.E.2d 728, 735 (1987) (same); *Klein v. Sears, Robuck & Co.*, 92 Md. App. 477, 608 A.2d 1276, 1284, *cert. denied*, 328 Md. 447, 614 A.2d 973 (1992) (same); *Henningsen v. Bloomfield Motors, Inc.*, 32 N.J. 358, 161 A.2d 69, 100-102 (1960) (same).

Appellants' breach of express warranty claim seeks damages for personal injuries, which are recoverable in Pennsylvania as consequential damages for breach of warranty. 13 Pa.C.S.A. §2715(b)(2). Given the substance of appellants' warranty claim and that "a consortium claim is inextricably intertwined with the underlying action for personal injury...[,]" *Novelli v. Johns-Mansville Corp.*, 395 Pa.Super. 144, 576 A.2d 1085, 1088 (1990), *appeal denied*, 527 Pa. 625, 592 A.2d 45 (1991), we think the Pennsylvania Supreme Court would permit Mrs. English to maintain her loss of consortium claim.

Finally, appellants argue that the Amendments do not preempt their claim that Mentor failed to comply with FDA

requirements in the design and manufacture of the device. The district court rejected this argument because appellants did not properly allege that Mentor failed to comply with FDA regulations concerning the manufacturing process. Appellants point to no evidence that would support or create an issue of fact with respect to such a claim, even if properly alleged. We find no error in the district court's determination. *See also Mendes v. Medtronic,* 18 F.3d 13, 20 (1st Cir. 1994) (refusing to consider the same argument where plaintiffs complaint contained no allegations of manufacturer's failure to comply with FDA requirements).

III.

The second issue raised by appellant is whether §§ 360k(a) preemption also applies to a Class III device without Premarket Approval, but cleared for marketing by a "substantial equivalence" determination. To reiterate, a manufacturer can bypass the full-blown Premarket Approval process if the FDA determines that the device is substantially equivalent to devices on the market before the Amendment became effective In 1976. 21 U.S.C. §§ 360e(b)(1): see discussion *supra* part II.

FDA regulations require that a manufacturer seeking a substantial equivalence determination submit a 510(k) Premarket Notification containing "an adequate summary of any information respecting [the] safety and effectiveness [of the device] or state that such information will be made available upon request by any person." 21 U.S.C. § 360c(i)(3)(A). The actual summary regarding the safety and effectiveness of the device must contain "detailed information regarding

data concerning adverse health effects and shall be made available to the public by the [FDA] within 30 days of the issuance of a determination that such device is substantially equivalent to another device. *Id.* §360c(1)(3)(B).

Moreover, the FDA regulates both the format and content of a 510(k) Notification. The Notification must include, among other things: any action taken by the manufacturer to comply with the Amendment's requirements for performance standards; proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use; where applicable, photos or engineering drawings of the device; a statement that the device is similar to and/or different from other products of comparable type, accompanied by data to support the statement that may include an identification of similar products, materials, design considerations, and a description of the operational principles of the device; and any additional information requested by the FDA that is necessary for it to make a finding of substantial equivalency. 21 C.F.R. § 807.87.

In addition to the requirements pertaining specifically to substantially equivalent devices, the devices are also subject to the FDA's "General Controls" which include labeling requirements and good manufacturing practices. *Mendes*, 18 F.3d at 14 (citing 21 U.S.C. §§ 360i, 360j). The parallel FDA regulations on labeling govern the content and appearance of prescription medical device labels. 21 C.F.R. §§ 801.1. 801.15, 801.109. As the *Mendes* court noted, these regulations exempt such devices from

the requirement that there be directions to a layperson on how to use the product safely, if the package describes, *inter alia*, "any relevant hazards, contraindications, side effects, and precautions" for the prescribing physician. *Id.* at 18 (quoting 21 C.F.R. §801.109). Furthermore, the FDA has promulgated extensive regulations interpreting the Amendments good manufacturing practices requirements. 21 C.F.R. §§820.1-820.198.

Only a handful of federal courts have considered whether the 510(k) process is a "requirement" that preempts state law tort under 21 U.S.C. §360k(a). The majority of them hold that it is a requirement. For example, in *Mendes, supra*, the court held that a FDA determination of substantial equivalence carries with it sufficient federal requirements relating to safety and effectiveness to preempt Duvall state law claims. *Accord Duvall v. Bristol-Myers Squibb Co.*, No. S-93 1072, 1994 WL 591534 (D. Md. Mar. 30, 1994); *Bollier v. Medtronic, Inc.*, No. H-92-2439, 1993 Wl 734843 (S.D. Tex. Oct. 28, 1993); *Rutland v. Mentor Corp.*, No. 20235, 1994 WL 454741 (Miss. Cir. Feb. 23, 1994).

With respect to Mentor's penile implants, the *Rutland* court stated:

> The application procedure under 510(k) includes extensive qualification criteria based upon clinical studies, drawings and procedures in the manufacture of the device, proposed labelings and warnings, extensive product sterility information and documentation, a comparison to other devices on the market and

> safety and effectiveness status based upon ten (10) years of another similar device. Mentor not only complied with the 510(k) requirements, it continues to comply with post-510(k) requirements imposed by law.

Id. at *3.

Among the few suggesting that the 510(k) process does not invoke preemption is *Larsen v. Pacesetter Systems, Inc.*, 74 Haw. 1, 837 P.2d 1273 (1992) (involving pacemaker). *Larsen* held that the 510(k) process does not preempt state law claims because it does not constitute FDA approval of a device. *Id.* at 1282. The court cited 21 C.F.R. § 807.97, which states that an FDA determination of substantial equivalence "does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the [510(k) Notification] regulations is misleading and constitutes misbranding." *Id.*

Nevertheless, we agree with the district court's well-reasoned rationale that the Amendment's preemption provision is triggered not by FDA approval of a device's safety and effectiveness, but by federal requirements relating to a device's safety and effectiveness. *See* 21 U.S.C. §360k(a). Those regulations include the 510(k) process with which a manufacturer must comply to obtain a determination of substantial equivalence. We are satisfied that this process sufficiently rigorous to constitute a "requirement"... relating to the safety or effectiveness" of Class III medical devices, pursuant to §360k(a).

Implicitly conceding that the FDA regulations discussed above do establish safety requirements, English nevertheless maintains that only regulations specifically covering inflatable penile prostheses have preemptive effect. In support of this argument, English asserts that the FDA has determined that preemption only applies when:

> [T]he [FDA] has established *specific* counterpart regulations or there are other *specific* requirements applicable to a *particular device* under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements. There are other State or local requirements that affect devices that are not preempted by section [360k(a)] of the act because they are "not requirements applicable to a device" within the meaning of section [360k(a)] of the act.

21 C.F.R. § 808.1(d) (emphasis added). Indeed, two district courts have followed this logic and ruled that preemption occurs only when there are specific, but not general, regulations pertaining to a device. *Ginochio v. Surgikos, Inc.* 864 F. Supp. 948, 951-53 (N.D. Cal. 1994); *Oja v. Howmedica, Inc.*, 848 F. Supp. 905, 906 (D. Colo. 1994).

We find this argument unconvincing. First, English attempts to read the phrase "other specific requirements applicable to a particular device" out of the statute.

This phrase suggests that a general regulation that is binding on a particular device has preemptive effect. *See Hodgon v. Mentor Corp.*, No. 92-1429, slip. op. at 5 (S.D. Ind. Aug. 8, 1994) (finding premarket approval regulations are "specific requirements" within meaning of § 808.1(d)); *Tucker v. Collagen Corp.*, 1994 U.S. Dist. LEXIS 3101, at *9 (N.D. Ill. Mar. 16, 1994) (rejecting narrow reading of §808.1(d)). Indeed, other circuits have relied on FDA regulations generally applicable to Class III devices in order to find preemption. *See Mendes*, 18 F.3d at 17-18 (good manufacturing practice and labeling requirements); *Stamps v. Collagen Corp*, 984 F.2d 1416, 1422 n.5 (5th Cir.) (good manufacturing practice requirements), *cert. denied*,___ U.S. ___, 114; S.Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1131 (1st Cir.) (premarket approval application requirements), *cert. denied*, ___ U.S. ___, 114 S.Ct. 84 (1993).

Second, even assuming that the FDA's regulations should be interpreted as English suggests, we believe no deference is owed to that interpretation because it conflicts with the text of the statute. *See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43, 104 S.Ct. 2778, 2781 (1984). Here, Congress directed that state requirements are preempted "which are different from, or in addition to, *any requirement* under [the FDCA]." 21 U.S.C. §360k(a) emphasis added). Thus, the mere fact that the FDA has promulgated regulations affecting groups of devices, rather than a specific type of device, should not alter whether or not there is preemption. *See Talbot v. C.R.*

Bard, Inc., 865 F.Supp. 37, 49 (D. Mass. 1994) (rejecting FDA's interpretation of preemption provision as contrary to statute); *Ministry of Health, Province of Ontario, Canada v. Shirley Inc.*, 858 F. Supp. 1426, 1436 (C.D. Cal. 1994) (same); *see also Stamps*, 984 F.2d at 1421 n.2 (interpreting §360k(a) and §808.1(d) as announcing "essentially the same test"); *King*, 983 F.2d at 1130 (ruling that §360k(a) provides "maximum protection and express preemption....").

Finally, since promulgating §808.1(d), the FDA has issued an interpretation of §808.1(d) contradictory to the one advanced by English. The FDA has stated: "[P]reemption is not restricted to State requirements that directly conflict with Federal law, but rather extends to requirements that are different from, or in addition to, *any* requirement applicable to the device under the act." 45 Fed. Reg. 67,326, 67,328 (1980) (emphasis added). Thus, we conclude that the FDA's labeling and good manufacturing practices regulations establish requirements within the meaning of §360k(a).

IV.

In conclusion, based on our decisions in *Gile* and *Michael*, we hold that appellants' strict product liability, negligence and breach of implied warranty claims are preempted by the Medical Device Amendments of 1976. Furthermore, we hold that preemption applies even where, as here, a Class III medical device is cleared for marketing under the "substantial equivalence" exception to the MDA Premarket Approval process. We hold, nonetheless, that the district court erred by granting

summary judgment in Mentor's favor on appellants' breach of express warranty claim. Under our holding in *Michael*, such a claim is not preempted by the MDA.[4] We will reverse and remand the cause for further proceedings on this claim.

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[4]For the reasons stated, we also remand Mrs. English's loss of consortium claim; however, we affirm summary judgment on appellants' claim for punitive damages.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

HUGH EDWARD ENGLISH, III	:	CIVIL ACTION
and LORRAINE ENGLISH	:	
v.	:	
MENTOR CORPORATION	:	
	:	No. 93-2725

MEMORANDUM AND ORDER

Yohn, J. June, 10, 1994

Both the plaintiffs and the defendant have moved for summary judgment in this products liability action based upon an allegedly defective penile prosthesis manufactured by defendant Mentor Corporation ("Mentor") and implanted in plaintiff Hugh English ("English"). For the reasons discussed below, the court will grant Mentor's motion for summary judgment and consequently deny English's.

I.

A.

In February of 1988 English had a Mentor GFS Inflatable Penile Prosthesis ("the prosthesis") implanted. Sometime in either the Summer or Fall of 1991 the prosthesis began to malfunction. On March 16, 1992 the malfunctioning prosthesis was removed by English's urologist and replaced with a Mentor Mark II Penile Prosthesis. On April 22, 1993, English and his wife instituted this action in the Philadelphia County Court of Common Pleas.

Their complaint asserts various product liability claims under Pennsylvania state law. Specifically, it alleges strict product liability, negligence in the design,

manufacture, labelling, and marketing of the prosthesis, and breach of implied and express warranties of merchantability.[1] On May 24, 1993, mentor timely removed this action to this court on the basis of diversity jurisdiction. Mentor now contends that all of the Englishs' claims are preempted by the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetics Act ("FDCA") and that it is thus entitled to judgment as a matter of law.

B.

Congress enacted the FDCA in 1938, delegating to the Food and Drug Administration ("FDA") authority to promulgate regulations to enforce the Act. *See* 21 U.S.C. §371(a). In 1976, Congress enacted the MDA, granting the FDA comprehensive and exclusive regulatory authority over medical devices. *Id.* §§360c-3601.

Under the MDA, all medical devices intended for human use are classified into one of three categories in order to provide a reasonable assurance of their safety and effectiveness: Class I devices such as tongue depressors generally pose little or no threat to public health and safety and accordingly are subject only to general controls on manufacturing processes. *Id.* §360c(a)(1)(A). Class II devices such as bone-conduction hearing aids are more complex and thus may be subject to special controls including "the promulgation of

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[1]English's wife also brought a loss of consortium claim. A claim of negligent misrepresentation originally contained in the complaint has since been withdrawn.

performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines..., recommendations, and other appropriate actions [that the FDA] deems necessary...." *Id.* §360c(a)(1)(B). Finally, Class III devices such as Mentor's prosthesis which "present[ ] a potential unreasonable risk of illness or injury," are subject to the most stringent regulation -- the premarket approval ("PMA") process -- before they may be marketed to the public. *Id.* §360c(a)(1)(C)(ii)(II).

The PMA process requires the manufacturer of a Class III device to submit a detailed application to the FDA that must include information pertaining to investigations relating to safety and effectiveness, product specifications, intended use, manufacturing methods, and proposed labeling. *Id.* §360e(c)(1). The FDA generally refers each application to a panel of qualified experts that prepares a report and recommendation with respect to the approval of the application. *Id.* §360e(c)(2). Within six months, the FDA must either accept or reject the application for PMA. *Id.* §360e(d).

Although as a general rule a Class III device must obtain PMA before it can be marketed to the public, *id.* §360e(a), that rule has two exceptions: First, Class III devices that are found by the FDA to be "substantially equivalent" to devices on the market before the MDA became effective in 1976 are entitled to bypass the PMA process unless or until the FDA issues a regulation specifying that the device undergo the PMA review process. *Id.* §360e(b)(1). And second, Class III devices that obtain an

investigational device exemption ("IDE") from the FDA, *id.* §360j(g), may be clinically tested on human subjects without first obtaining PMA. *Id.* §360e(a)[2]

In this instance, on August 26, 1987, the FDA determined that Mentor's prosthesis was substantially equivalent to other Class III devices marketed prior to the enactment of the MDA and thus permitted Mentor to market its prosthesis to the public without obtaining PMA. Moreover, before Mentor requested authorization from the FDA to market its prosthesis, it had applied for and received an IDE permitting it to test the device on human subjects. The implantation of English's prosthesis, however, was not part of a clinical trial conducted pursuant to Mentor's IDE but rather occurred after the device had been cleared for marketing to the public via the FDA's substantial equivalence determination.

C.

The Supremacy Clause of the United States Constitution provides that federal law "shall be the Supreme Law of the Land." U.S. Const. art. VI, cl. 2. State laws that conflict with federal statutes and regulations are thus preempted. *See Cipollone v. Liggett Group*, 112 S.Ct. 2608, 2617 (1992). It is well settled that the intent of Congress is the touchstone of preemption analysis. *Id.* "Congress' intent

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[2]A more thorough explanation of the IDE process may be found in *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S.Ct. 327 (1992) and *Gile v. Optical Radiation Corp.*, F.3d 1994 U.S. App. LEXIS 9586 (3d Cir. May 3, 1994).

preemption analysis. *Id.* "Congress' intent may be 'explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" *Id.* (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

The MDA contains a provision that expressly addresses its intended preemptive scope:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement ---
>
> (1) which is different from, or in addition to, any requirement applicable under [the FDCA] to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA].

21 U.S.C. §360k(a). By regulations the validity of which is not in question, the FDA has declared that preemption, though equally applicable whether the state is acting "by statute, ordinance, regulation, or court decision," is limited to cases in which the FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device under [the FDCA]." 21 C.F.R. §§808.1(b),(d).

In *Slater v. Optical Radiation Corporation*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S.Ct. 327 (1992), Judge Posner described the preemption provision of the MDA as follows: "If the FDA in a valid

regulation under the [MDA] requires X, and X relates to safety or effectiveness, a state cannot, whether through statute, regulation, or common law decision, require non-X, or X + Y." *Id.* at 1333. The Fifth Circuit offers a slightly different interpretation of the preemption provision:

> A state tort cause of action will be preempted if, in the context of the particular case, it (1) constitutes a requirement different from, or in addition to, any requirement the MDA makes applicable to the device at issue and (2) relates either to (a) the safety or effectiveness of the device or (b) any other matter included in a requirement made applicable to the device by the MDA.

Stamps v. Collagen Corp., 984 F.2d 1416, 1421 (5th Cir.) (footnote omitted), *cert. denied*, 114 S.Ct. 86 (1993); *see also King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.) (applying similar test to identical product), *cert. denied*, 114 S.Ct. 84 (1993).

D.

Both the First and Seventh Circuits, as well as a district court within the Third Circuit, have found the PMA process to be a "requirement" within the meaning of §360k(a) that preempts state requirements relating to the safety or effectiveness of a device, including common law causes of action, that are either different from or in addition to the requirements contained in the PMA process. *See King, supra; Stamps, supra*, 984 F.2d at 1421 ("Simply put, [state] tort liability...would constitute a requirement either different from, or in addition to, a

requirement -- the Class III PMA process -- that the MDA has made applicable to [the medical devices in question]"); *Michael v. Shiley, Inc.*, 1994 WL 59349, *7 (E.D.Pa. Feb. 25, 1994) ("the premarket approval process and post-approval regulations are "requirements" within the meaning of §360k(a) that preempt Pennsylvania law claims"), *appeal docketed*, No. 94-1496 (3d Cir. May 3, 1994). Thus, where a Class III medical device has obtained PMA, courts have consistently held that state products liability claims asserted against such a device are preempted by the MDA. *See, e.g., King* (strict liability, negligence (in the design, manufacture, marketing, and sale of the device), breach of warranty of merchantability, misbranding and/or mislabeling, failure to warn, and fraud on the FDA claims preempted); *Stamps* (inadequate labeling, failure to warn, and defective design and manufacture claims preempted); *Michael* (strict products liability, negligence, failure to warn, and breach of implied warranty claims preempted).

II.

English contends that his state law products liability claims should not be preempted by the MDA because Mentor's prosthesis never obtained PMA from the FDA but rather reached the public via the FDA's substantial equivalence determination.[3] He

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[3]English's additional contention that state tort common law claims are not preempted by the MDA is plainly wrong. See 21 C.F.R. §808.1(b) (no "State...may

(continued...)

contends that the substantial equivalence process is much less rigorous than the PMA process and thus not the type of "specific requirement" under the MDA that preempts state requirements. The issue squarely before the court, therefore, is whether the MDA's substantial equivalence process is, like the PMA process, a "requirement" within the meaning of §360k(a) that preempts state requirements, including common law causes of action, relating to the safety or effectiveness of a device.

A.

With regard to a medical device compared to a predicate device already on the market prior to the enactment of the MDA, the term "substantial equivalence" or "substantially equivalent" means that:

> [T]he device has the same intended use as the predicate device and that the [FDA] has found that the device --
>
> (i) has the same technological characteristics as the predicate device, or
>
> (ii) (I) has different technological characteristics and

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[3](...continued)
establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation or court decision)") (emphasis added); *Gile v. Optical Radiation Corp.*, F.3d 1994 U.S. App. LEXIS 9586, *6-9 (3d Cir. May 3, 1994) (MDA preempts state tort common law claims as well as positive legislative enactments).

> the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and efficacy than the predicate device.

21 U.S.C. §360c(i)(1)(A).

A manufacturer that intends to market a medical device pursuant to the substantial equivalence process must submit a premarket notification ("a 510 (k) Notification") to the FDA at least 90 days before it proposes to introduce the device into interstate commerce for commercial distribution. 21 C.F.R. §807.81. The 510(k) Notification must contain "an adequate summary of any information respecting [the] safety and effectiveness [of the device] or state that such information will be made available upon request by any person." 21 U.S.C. §360c(i)(3)(A). The summary regarding the safety and effectiveness of the device must contain "detailed information regarding data concerning adverse health effects and shall be made available to the public by the [FDA] within 30 days of the issuance of a determination that such device is substantially equivalent to another device." *Id.* §360c(i)(3)(B).

The FDA has issued regulations regarding both the format of a 510(k) Notification, 21 C.F.R. §807.90, and the information required to be contained in a 510(k) Notification. *Id.* §807.87.

Specifically, a 510(k) Notification must include the following information: the device's name; the manufacturer's registration number; the classification of the device, and, if known, its appropriate panel; any action taken by the manufacturer to comply with the MDA's requirements for performance standards; proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use; where applicable, photographs or engineering drawings of the device; a statement indicating that the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement that may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device; and any additional information regarding the device requested by the FDA that is necessary for the FDA to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. *Id.*

In this instance, Mentor filed a 510(k) Notification for its prosthesis on June 9, 1987. (*See* Def.'s Mem. Supp. Summ. J. at Ex. A.) This 510(k) Notification included all of the information referenced above as well as a summary of a nine-month clinical evaluation conducted pursuant to the prosthesis' FDA-approved IDE. (*Id.*) Moreover, the 510(k) Notification incorporated data that was submitted as part of the device's IDE application, including: "Clinical Investigation Protocol, Clinical

and Biological Testing, Physical and Mechanical Testing, Manufacturing and Quality Procedures, Sterilization Procedures, and Biological Test Reports." (*Id.; see also* Def.'s Reply Mem. Supp. Summ. J at Ex. A.)

On August 26, 1987, after reviewing Mentor's 510(k) Notification, the FDA determined that the prosthesis was substantially equivalent to devices marketed in interstate commerce prior to the enactment of the MDA and therefore approved the marketing of the prosthesis subject to the general controls provisions of the FDCA including the MDA's good manufacturing practice requirements. (*See* Def.'s Mem. Supp. Summ. J. at Ex. A.) Additionally, the FDA noted that the prosthesis, as a Class III device, would be required to undergo PMA at some time in the future and that its substantial equivalence determination did not "in any way denote official FDA approval of [the prosthesis] or its labeling." (*Id.*)

B.

English contends that no circuit court of appeals has ever directly addressed the issue of whether the substantial equivalence process is, like the PMA process, a "requirement" within the meaning of §360k(a) that preempts state requirements, including common law causes of action, relating to the safety or effectiveness of a device. That is not entirely accurate.

Recently, the First Circuit upheld a district court's grant of summary judgement in favor of a manufacturer of a pacemaker *that had not obtained PMA but rather was distributed pursuant to a substantial equivalence determination* on the ground that

the MDA preempted plaintiff's Massachusetts common law claims. *Mendes v. Medtronic*, 18 F.3d 13, 15 (1st Cir. 1994). There, plaintiff's complaint had alleged negligence in the design, manufacture, and distribution of her pacemaker, a Class III device, as well as claims for failure to warn and breach of implied warranty of merchantability. *Id.* at 15. Because the court deemed plaintiff to have abandoned her defective design claim, it declined to consider "her argument that, in the absence of a requirement that the device receive premarket approval, her design defect claims are not preempted." *Id.* at 18. The court nevertheless found that her "negligence and implied warranty claims premised on inadequate warnings [were] preempted" because the "FDA regulates the content and appearance of prescription medical device labels, including pacemaker labels." *Id.* (citing 21 C.F.R. §§ 801.1, 801.15, 801.109). Similarly, the court found that her implied warranty claim and "negligent manufacturing claim (including her allegations of negligent manufacturing, control, maintenance, inspection, testing, servicing, distribution, and sale of the device) [were] preempted by FDA regulations on good manufacturing practices. 21 C.F.R. §§ 820.1-820.198." *Id.* at 19.

Moreover, Mentor has brought this court's attention to three cases wherein other courts have held that preemption under the MDA should attach even in the absence of PMA. *See Duvall v. Bristol Myers*, No. S 93-1072 (D.Md. March 30, 1994); *Rutland v. Mentor Corp.*, No. 20,235 (Harrison County, Miss. Cir. Ct. Feb. 23, 1994); *Bollier v. Medtronic, Inc.*, No. H-92-2439 (S.D.Tex.

Oct. 27, 1993). In all of those cases, the respective courts considered and rejected the argument that preemption should not occur because the substantial equivalence process was less stringent than the PMA process. While the *Bollier* court limited its analysis, noting only that "[a]lthough the [substantial equivalence] process is not as comprehensive as that imposed through the PMA [its] requirements are substantial," *id.*, slip op. at 3, the *Duvall* and *Rutland* courts examined the issue in greater detail.

In *Duvall*, the court felt that with the exception of plaintiff's design defect claim, *Mendes* compelled the conclusion that the other state law claims were preempted even though the penile implant in question had never obtained PMA but rather reached the market via the substantial equivalent process. *Id.*, slip op. at 2. With regard to the design defect claim not reached in *Mendes*, the court opined that:

> [A]lthough the [substantial equivalence] process, governed by the detailed provisions of the MDA itself, *viz.*, 21 U.S.C. § 360c(i)(A), is not so complex as the pre-marketing approval (PMA) process for newly contrived devices, [it] is nonetheless both rigorous and designed completely to control the marketer's market behavior with regard to the device, which is after all, the foundation for the pre-emption analysis in the first place. Certainly, at least in this case, there was a requirement that the [substantial equivalence] request be supported with clinical test

> data subject to agency scrutiny before marketing approval was bestowed.

Id. slip op. at 2-3. Accordingly, the court granted summary judgment for the manufacturer on the design defect claim.

> In *Rutland*, the court noted that: [The substantial equivalence process] . . . includes extensive qualification criteria based upon clinical studies, drawings and procedures in the manufacture of the device, proposed labelings and warnings, extensive product sterility information and documentation, a comparison to other devices on the market and safety and effectiveness status based upon ten (10) years of another similar device.

Id., slip op. at 6. Citing 21 U.S.C. §§ 360c(f)(3), 360c(i)(3)(A), 360c(i)(3)(B), and 21 C.F.R. § 807.87, the court found that "Congress and the FDA have established specific requirements 'relating to' the safety and effectiveness of the medical device which must be followed in order to obtain the substantial equivalent status." *Id.*, slip op. at 3. Thus, because "[t]he requirements and regulations for permission to market a medical device under [the substantial equivalence process] constitute specific relations made applicable to inflatable penile implants and relate to the safety or effectiveness of the device," *id.*, slip op. at 4, the court held that the plaintiff's state law claims were preempted by the MDA.

English relies mainly upon *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273

(Haw. 1992) and *Stamps*, *supra*. In *Larsen*, the Hawaii Supreme Court held that the MDA did not preempt state law claims asserted against the manufacturer of an allegedly defective pacemaker because there were "no specific statutes or regulations applicable to the . . . device." *Id.* at 1282. This holding was premised upon the conclusion that "the statutes and regulations governing premarket approval set forth general procedural requirements and, therefore, do not trigger a preemption analysis." *Id.* As an alternate ground for its decision the court pointed out that the pacemaker had reached the market via the substantial equivalence process rather than the PMA process, and in that regard noted that in the legislative history of the 1990 amendments to the MDA, Congress had stated:

> [O]ver 80 percent of the devices that are potentially the most dangerous (Class III) enter the market on the basis of a claim by the manufacturer that they are "substantially equivalent" to a device already on the market. Although a determination of substantial equivalence involves a review by the FDA of what is known of the safety and effectiveness of the devices, and may even include some additional clinical testing, it is not equivalent to an approval by the FDA of the device's safety and effectiveness.

Id. (citation omitted). The court also cited 21 C.F.R. § 807.97 which states that a substantial equivalence determination by

the FDA does not in any way denote official approval of the device, and concluded:

> Thus, meritorious claims of the type brought by plaintiff would not contravene FDA "approval" of the device and would further Congressional intent by providing pacemaker manufacturers a product safety incentive in those areas where the premarket approval process has failed adequately to protect the consumer.

Id.

English contends that in *Stamps*, the Fifth circuit cited *Larsen* for the proposition that preemption should not occur where a device reaches the market via the substantial equivalence process rather than through the more stringent PMA process, and that *Stamps* thus supports a conclusion that a substantial equivalence determination should not trigger preemption under the MDA. (*See* Pls.' Mem. Opp'n Summ. J. at 14 (citing *Stamps*, 984 F.2d at 1423 n.6.)) The court disagrees; English's contention misconstrues *Stamps'* analysis of *Larsen* and perhaps even the actual holding in *Larsen*.

In *Stamps*, which involved a Class III device that had obtained PMA, the plaintiff contended that "the MDA preempts state law only to the extent that the state mandates a similar PMA process." *Id.* at 1423. The court rejected this argument, concluding instead that "[state] PMA processes are preempted in addition to any other state requirements relating to safety or effectiveness or any other MDA requirement established for the device." *Id.* (emphasis added) (footnote omitted). In reaching this conclusion the court noted *Larsen's* holding

that the PMA process merely set forth general procedural requirements that did not trigger a preemption analysis, but distinguished Larsen on the ground that "it involved a device that passed through a less stringent Class III review process by virtue of its being 'substantially equivalent' to devices already allowed to be marketed." *Id.* at 1423 & n.6. *Stamps'* analysis of *Larsen* thus provides no direct support for the proposition that a substantial equivalence determination should not trigger a preemption analysis under the MDA for it simply did not squarely address that question. Rather, *Stamps* distinguished *Larsen* in the course of declining to follow *Larsen's* holding that the PMA process does not trigger a preemption analysis under the MDA.

Moreover, *Larsen* itself may not stand squarely for the premise that preemption should not occur where a device reaches the market via the substantial equivalence process rather than through the more stringent PMA process. Its conclusion that plaintiff's claim was not preempted rested in large part upon its determination that the PMA process did not trigger a preemption analysis under the MDA because it merely "set forth general procedural requirements" and was thus not a "specific statute[] or regulation[] applicable to the particular device in question." *Id.*, 837 P.2d at 1282. This aspect of its holding is contrary to the vast weight of authority including *Stamps*, *King*, *Michael*, and *Mendes*, *supra*, and in the court's view is no longer

tenable.[4] *Larsen's* analysis of the preemptive effect of a substantial equivalence determination is thus undercut because it relies at least implicitly upon the rationale that general procedural requirements -- whether the PMA process or the less stringent substantial equivalence process -- do not trigger a preemption analysis under the MDA.[5]

C.

The court finds the reasoning employed by the *Mendes*, *Bollier*, *Duvall*, and *Rutland* courts more persuasive than that employed by the *Larsen* court and accordingly will follow their conclusion that preemption under the MDA applies even where a Class III medical device reaches the market via the substantial equivalence process. For, although that process may not be as rigorous or complex as the PMA process, "[t]he

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[4]Indeed, the court is aware of no other opinion -- nor has English cited another -- holding that the PMA process does not trigger a preemption analysis under the MDA.

[5]It might perhaps also be argued that *Larsen's* analysis of the preemptive effect of a substantial equivalence determination is only dicta because it was offered as an alternative to the holding that the PMA process did not trigger a preemption analysis. The court in *Mendes* did, however, cite *Larsen* as standing for the proposition that "design defect claims are not preempted where FDA never approved device design because device was found to be substantially equivalent to pre-MDA devices." *Mendes*, 18 F.3d at 18.

requirements and regulations for permission to market a medical device [pursuant to a substantial equivalence determination] constitute specific regulations made applicable to inflatable penile implants and relate to the safety or effectiveness of the device." *Rutland*, slip op. at 4. Here, as was the case in *Duvall*, Mentor's 510(k) Notification was supported with clinical test data subject to FDA scrutiny before marketing approval was bestowed -- specifically, Mentor's 510(k) Notification incorporated its FDA-approved IDE application that contained extensive information, including a nine-month clinical evaluation, relating to the prosthesis's safety and effectiveness. *See also Rutland*, slip op. at 6 ("[The substantial equivalence] procedure... includes extensive qualification criteria based upon clinical studies, drawings and procedures in the manufacture of the device, proposed labelings and warnings, extensive product sterility information and documentation, a comparison to other devices on the market and **safety and effectiveness status based upon ten (10) years of another similar device**") (emphasis added).[6]

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[6]Currently, a 510(k) Notification must contain "an adequate summary of any information respecting [the] safety and effectiveness [of a device]," 21 U.S.C. §360c(i)(3)(A), and a substantial equivalence determination means that the FDA has found that the information submitted in the 510(k) Notification demonstrates that the device is as safe and effective as a

(continued...)

Moreover, while *Stamps* analysis of *Larsen* might, as English contends, lend some remote inferential support to the premise that preemption should not occur on the basis of a substantial equivalence determination, other portions of the *Stamps'* opinion strongly counsel a contrary conclusion. *See Stamps*, 984 F.2d at 1423-24 ("[T]he literal language of [21 U.S.C. § 360k(a)] compels this result: State requirements pertaining to the safety or effectiveness of a device, or to any other matter included in a requirement made applicable to the device by the MDA, are preempted whenever they are different from, or in addition to, **any requirement** imposed upon the device under MDA") (emphasis added); *id.* at 1424 n. 8 ("It is plain that [21 C.F.R.] § 808.1(d) poses the same test as [21 U.S.C. § 360k(a)]: When there exists a **specific requirement** applicable to a particular device under the act...additional or different state laws are preempted") (emphasis added); *see also Rutland*, slip op. at 7 ("*Stamps* supports pre-emption because classification of the device as Class III

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[6](...continued)
legally marketed device, *id.* §(i)(1)(A)(ii)(I). Subsection (i) to §360c was added in the 1990 amendments to the MDA and thus its requirements were not applicable to the prosthesis in question. Nevertheless, as noted above, the 510(k) Notification for that prosthesis incorporated Mentor's previously approved IDE application that contained extensive information regarding the device's safety and effectiveness.

subjects it to the beginning phases of the PMA process and because the [substantial equivalence] process imposes significant safety and effectiveness requirements").

As *Stamps* notes, the MDA's preemption provision speaks only of "*any requirement* imposed upon the device" and "*a specific requirement* applicable to a particular device." There is no mention of any sort of threshold level of stringency that a requirement must meet before preemption can attach, and the court is unwilling to engraft such a requirement onto the statute. It is for the FDA, not this court, to determine how rigorous or lenient it wishes its regulations to be. As the court reads § 360k(a), it is the *existence* of a regulation relating to safety or effectiveness of a device rather than the level of stringency of such a regulation that triggers preemption under the MDA.[7]

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[7]The legislative history referenced in *Larsen* that English relies upon is likewise unavailing. Congress' statement in the 1990 amendments to the MDA that a substantial equivalence determination "is not equivalent to an approval by the FDA of [a] device's safety and effectiveness," see *Larsen*, 837 P.2d at 1282, does not compel a conclusion that preemption under the MDA cannot occur unless a device has obtained PMA. The MDA's preemption provision is triggered not by official FDA approval of a device's safety and effectiveness but by FDA regulations -- such as those contained in the substantial equivalence process -- relating to a device's safety or effectiveness. 21 U.S.C. §360k(a).

Finally, the court notes that a conclusion that English's claims are preempted is buttressed by other sections of the MDA and applicable FDA regulations. In *Mendes*, the First Circuit found that negligence and warranty claims premised on inadequate warnings were preempted because 21 C-F.R. §§ 801.1, 801.15, 801.109 regulate "the content and appearance of prescription medical device labels." *Id.*, 18 F.3d at 18. Likewise, warranty and negligence claims stemming from alleged defective manufacturing were preempted by the general good manufacturing practice requirements of the MDA, 21 U.S.C. § 360j(f), and applicable FDA regulations, 21 C.P.R. §§ 820.1 - 820.198. *Id.* at 19; *see also Stamps*, 984 P.2d at 1422 n.5 ("§ 360j(f)'s '[g]ood manufacturing practice requirements', impose further requirements upon the manufacture of Class III devices, leaving...little doubt as to whether the MDA tolerates different or additional state requirements, respecting design or manufacture, in the form of common law products liability duties"). Consequently, English's claims should be preempted because they would impose requirements relating to the prosthesis' safety or effectiveness that are additional to or different from either the above regulations or those regulations contained in the substantial equivalence process. English has, however, raised two additional arguments regarding his manufacturing defect claim that warrant further scrutiny.

D.

English contends that his manufacturing defect claim should not be preempted because: (1) Mentor failed to comply with the FDA's good manufacturing practice

requirements; and (2) the *particular* prosthesis implanted in English was defective. These two contentions dovetail with each other and are addressed below.

After oral argument on the summary judgment motions had been conducted, English supplemented his reply to Mentor's motion by supplying the court with an addendum report from his expert. In this addendum report, dated May 17, 1994, the expert opined that 'Mentor Corporation failed to conform to the Good Manufacturing Practices by inadequately controlling the molding process, resulting in molding flash which was not removed in subsequent procedures."[8] Thus, according to English, because "there is evidence that the manufacturing process in the specific [prosthesis] involved strayed from the

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[8]According to English's expert's original report of January 7, 1994, "plastic mold flash [is a molding defect that] occurs during the molding process when the plastic, flowing under pressure, flows between parts of the mold into unintended areas." (*See* Pls.1 Mem. Opp'n Summ J., Ex. D.) The addendum report contends that this "molding flash," as well as the often accompanying molding defect known as "voids" wherein the plastic does not flow into areas that it should, contributed to a leakage of fluid between the prosthesis' snap-lock connectors and its tubing that resulted in the prosthesis' failure. According to the addendum report, "[b]oth of these molding defects ["flash" and "voids"] are the result of improper manufacturing and inspection controls which violate the intent of the [FDA's] Good Manufacturing Practices."

accepted process.... preemption should not occur." (Pls.' Mem. Opp'n Summ. J. at 17.)

In *Reiter v. Zimmer, Inc.*, 830 F. Supp. 199 (S.D.N.Y. 1993), the court refused to extend the preemptive scope of the MDA to cover a claim of negligent manufacture where the manufacturer allegedly "did not comply with its own FDA approved manufacturing processes," instead denying the defendant manufacturer's motion for summary judgment on that claim and allowing discovery "on the subject of [the manufacturer's] compliance or noncompliance with the specifications set forth in the FDA's approval of [its device], "*Id.* at 204. *See also Slater, supra*, 961 P.2d at 1334 (scope of preemption under the MDA is limited to efforts by states to impose sanctions for compliance with federal regulations"); *but cf. King, supra*, (MDA preempted claim that defendant manufacturer fraudulently obtained PMA of device); *Kemp v. Pfizer*, 835 F. Supp. 1015 (E.D.Mich. 1993) (same).

In *Gondeau v. Mentor Corp.*, No. 1:92CV2149 (N.D.Ohio Nov. 22, 1993), the court noted that although the MDA precluded inquiry into the manufacturing methods of a device, it did not preclude inquiry into the manufacture of a particular device and thus denied summary judgment for the manufacturer on plaintiff's defective manufacture claim because there existed "a genuine issue of fact concerning whether the defendant defectively manufactured the particular prosthesis that was surgically implanted in [the plaintiff]." *Id.*, slip op. at 7 (emphasis added). Upon reconsideration, however, the court granted summary judgment for the manufacturer on the defective manufacture claim because it determined that

under controlling Ohio law such a claim was the equivalent of a strict liability claim and thus preempted by the MDA. *Gondeau v. Mentor Corp.*, No. 1:92CV2149 (N.D.Ohio Dec. 14, 1993), slip op. at 3.

In this instance, although English's complaint enumerates twenty-one (21) ways in which Mentor was negligent in the design, manufacture, and distribution of the prosthesis, (Compl. Paragraph 37), nowhere does it allege that Mentor failed to comply with the FDA's regulations on the manufacturing process. Absent such an allegation, any successful claim of defective manufacture, even one limited to the particular prosthesis in question, would result in a requirement different from or in addition the FDA's good manufacturing practice requirements in contravention of the MDA's preemption provision. Accordingly, Mentor is entitled to summary judgment an the defective manufacture claim.

III.

Mentor alternately contends that English's state law claims should be preempted because the prosthesis was granted an IDE by the FDA. In cases involving another Class III medical device, an intraocular lens, the Third, Seventh, and Eleventh Circuits have all held that obtaining an IDE preempted state-law claims. *See Gile v. Optical Radiation CORP.*, ___ F.3d ____, 1994 U.S. App. LEXIS 9586 (3d Cir. May 3, 1994); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S.Ct. 327 (1992); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994) (one paragraph per curiam opinion electing to follow *Slater*). English argues that those cases are inapposite because the

plaintiffs there were all injured during the clinical trial of the device that had obtained the IDE rather than after the device had been marketed pursuant to a substantial equivalence determination as was the case here. Because the court has determined that English's claims are preempted for the reasons discussed above, it is unnecessary for it to address the issue of whether obtaining an IDE preempts state-law claims where the plaintiff was not injured as part of a clinical trial conducted pursuant to the IDE.

IV.

For the reasons discussed above, the court concludes that all of English's claims are preempted by the MDA.[9] Therefore, Mentor is entitled to summary judgment. An appropriate order follows.

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[9]Because English's wife's claim for loss of consortium is contingent upon the claims preempted by the MDA, it too must fail.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

HUGH EDWARD ENGLISH, III and LORRAINE ENGLISH, Plaintiffs	: CIVIL ACTION
v.	:
MENTOR CORPORATION, Defendant.	: No. 93-2725

O R D E R

AND NOW, this 10th day of June, 1994, upon consideration of the parties' motions for summary judgment, and the briefs thereto, it is hereby **ORDERED** that Defendant Mentor Corporation's Motion for Summary Judgment is hereby **GRANTED** and plaintiffs Hugh and Lorraine English's motion for summary judgment is hereby **DENIED**. Summary judgment on all counts of plaintiffs' complaint is entered in favor of the defendant and against the plaintiffs.

It is further **ORDERED** that both plaintiff's and defendant's motions *in limine* are hereby **DENIED** as moot.[1]

It is further **ORDERED** that this action be marked closed for statistical purposes.

s/
William H. Yohn, Jr., Judge

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[1]Both plaintiffs and defendant alternatively fashioned their motions for summary judgment as motions *in limine*.

UNITED STATES COURT OF APPEALS
FOR THE THIRD COURT

No. 94-1714

HUGH EDWARD ENGLISH, III;
LORRAINE ENGLISH
v.
MENTOR CORPORATION

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA
(D.C. Civil Action No. 93-02725)

Present: COWEN, NYGAARD, and ALITO,
Circuit Judges

JUDGMENT

This cause came on to be heard on the record from the United States District Court for the Eastern District of Pennsylvania and was argued by counsel January 12, 1995.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the said District Court entered June 14, 1994, be, and the same is hereby reversed insofar as the District Court granted summary judgment in Mentor's favor on appellant's breach of warranty claim, affirmed with respect to appellant's claim for punitive damages, and remanded for further proceedings in accordance with the opinion of this Court. All of the above in accordance with the opinion of this Court.

ATTEST:
s/
Clerk

Dated: September 29, 1995

21 U.S.C. §360k State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-

(1) which is different from, or in addition to, any requirement applicable under the chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. §807.97 Misbranding by reference to premarket notification

Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

21 C.F.R. §807.100 FDA action on a premarket notification

(b) FDA will determine that a device is substantially equivalent to a predicate device using the following criteria:

(1) The device has the same intended use as the predicate device; and

(2) The device:

(i) Has the same technological characteristics as the predicate device; or

(ii)(A) Has different technological characteristics, such as a significant change in the materials, design, energy source, or other features of the device from those of the predicate device;

(B) The data submitted establishes that the device is substantially equivalent to the predicate device and contains information, including clinical data if deemed necessary by the Commissioner, that demonstrates that the device is as safe and as effective as a legally marketed device; and

(C) Does not raise different questions of safety and effectiveness than the predicate device.

21 C.F.R. 808.1 Scope

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a

particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g. requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(2)

Supreme Court, U.S.
FILED
FEB 8 1996
CLERK

No. 95-1034

In The

Supreme Court of the United States

October Term, 1995

HUGH ENGLISH, et ux.,

Petitioners,

v.

MENTOR CORPORATION,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF FOR RESPONDENT IN SUPPORT OF THE PETITION

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RESPONDENT'S BRIEF IN SUPPORT OF THE PETITION

SUMMARY

The broadly stated "Question Presented" by the petition (Pet. at i) actually subsumes three discrete questions. The first is whether the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a),[1] trigger preemption of a state law claim alleging defective design of a Class III medical device, where the FDA approved the release of the device to market under that agency's "510(k)" regulatory procedure.

Respondent Mentor Corporation[2] ("Mentor") agrees that the petition should be granted on that question, which is the same one presented in *Mentor Corp. v. Feldt*, No. 95-1037 (pending), and in *Medtronic, Inc. v. Lohr*, No. 95-754, *cert. granted*, January 19, 1996. The two Mentor cases should be consolidated with *Medtronic* for plenary consideration in order that the Court might have the benefit of a record of greater breadth upon which to consider the issue of preemption triggered by the 510(k) regulatory procedure.

Two other Medical Device Act preemption questions were also resolved against petitioner by the court below. These are whether Section 360k(a) also triggered preemption of petitioner's defective manufacturing and failure to

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[1] The text of the statute is printed at Pet. 63.

[2] Pursuant to Rule 29.6, we advise the Court that respondent Mentor has no parent company and no subsidiaries that are not wholly owned.

warn claims, where the device was manufactured in compliance with the FDA's good manufacturing practices regulations, and was marketed in compliance with the agency's labeling regulations.

In the petition in *Mentor Corp. v. Feldt*, Mentor took the position that these two questions concerning preemption of defective manufacturing and failure to warn claims were not cert-worthy because no mature circuit conflict had developed as to those issues. Since Mentor's petition in *Feldt* was filed, this Court granted certiorari to consider the cross-petition in *Medtronic*, No. 95-886. The cross-petition in *Medtronic* appears to present the preemption issues that arise from state law defective manufacturing and failure to warn claims. Thus, the *Medtronic* cross-petition seems to have now placed before the Court for consideration the preemptive consequences that arise from the FDA's good manufacturing practices regulations and the same agency's labelling regulations. In view of the grant of certiorari on the *Medtronic* cross-petition, Mentor would not oppose certiorari in this case for the purpose of also considering whether Section 360k(a) preempts petitioner's defective manufacturing and failure to warn claims, in circumstances where the device was manufactured in compliance with the FDA's good manufacturing practices regulations, and was marketed in compliance with the FDA's labeling regulations.

COUNTERSTATEMENT

This is a product liability case involving the alleged 1992 failure of a penile implant, a Class III medical device manufactured by respondent and installed some years earlier in the person of the petitioner, Hugh English. The case was removed from a Pennsylvania court under the diversity grant. Pet. at 35-36.

Typical of most product liability actions, petitioner's complaint assailed "defects" in the design and manufacture of the device, and also asserted a failure to warn claim. The district court granted summary judgment for respondent on the ground that all three categories of claim were preempted by reason of Section 360k(a) (Pet. at 35-61), and the court of appeals affirmed. *Id.* at 18-34, 62.[3]

The petition is inaccurate, however, in two respects. *First*, petitioner suggests that the 510(k) marketing approval of the FDA was the basis on which the court of appeals found statutory preemption of all three categories of claim. This is not correct. The opinion below makes clear that 510(k) approval triggered preemption of the "design defect" claim, but that the manufacturing defect and failure to warn claims were preempted for other reasons, namely, respondent's compliance with the FDA's good manufacturing practices and labeling regulations, respectively. *See* Pet. at 27-29. The latter is in full accord with other decisions, e.g., *Lohr v. Medtronic, Inc.*,

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[3] The court of appeals reversed the district court's ruling that an express warranty claim was also preempted (*see* Pet. at 33-34), but neither side seeks review of that point here.

56 F.3d 1335, 1350-52 (C.A. 11, 1995), *cert. granted*, January 19, 1996 (Nos. 95-754 and 95-886); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 399-400, (C.A. 4, 1995), *pet'n for cert. pending* (No. 95-1010); *Feldt v. Mentor Corp.*, 61 F.3d 431 (C.A. 5, 1995), *pet'n for cert. pending* (No. 95-1037); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 (C.A. 5), *cert. denied*, 114 S.Ct. 86 (1993).

Second, the petition suggests that because the FDA's 510(k) regulatory process may be somewhat less rigorous than the agency's alternative premarket approval ("PMA") process, the 510(k) process amounts to little more than witless agency approval of "grandfathered" devices. *See* Pet. at 14-16. This innuendo is also inaccurate. The record made in this case shows that respondent's 510(k) application included substantial data as to the safety and efficacy of the device, much of it the product of clinical trials conducted under an earlier-granted FDA Investigational Device Exemption. *See* Pet. at 38, 43-45 (district court's summary of the record before it).

REASONS TO GRANT THE WRIT

Although the question whether 510(k) approval by the FDA triggers preemption of design defect claims is now before the Court in *Lohr*, the Court should grant the petition here on that issue and in the companion case of *Mentor Corp. v. Feldt*, No. 95-1307. Petitioner's argument here, and the court of appeals' decisions in *Lohr* and *Feldt*, *supra*, cast aspersions on the efficacies of the 510(k) approval process. Although such aspersions are wide of the mark, the record in *Lohr* affords only a small glimpse

of the 510(k) process. Plenary examination of the present case, and of *Feldt*, would provide the Court with a record of greater breadth. For this reason, respondent supports and urges the plenary grant of review in this case and in *Feldt* in order to fully consider the question of 510(k) approval.

CONCLUSION

Certiorari should be granted, and the Court should use this case, in combination with *Lohr* and *Feldt*, to consider on a full record whether 510(k) approval triggers statutory preemption of design defect claims as to Class III medical devices.

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Respectfully submitted,

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